

### **REMARKS**

Claims 1-47 are pending. Claims 4-41 are withdrawn from consideration. Claims 1-3 and 42-47 remain in the application. Claims 1-3 are currently amended to better conform with the specification and no new matter is introduced. Applicants expressly reserve the rights to rejoin Group IV with Group I in accordance with MPEP § 821.04. Applicants also expressly reserve the rights to pursue the withdrawn claims in a divisional application.

#### **Claim Rejections - 35 U.S.C. § 103(a)**

Claims 1-3 and 42-47 stand rejected under 35 U.S.C. § 103(a) as being obvious over Chen (Zhongguo Yigao Gongye Zazhi, 1993, 24(6), pages 241-242), Tyers (US Pat. 4,845,115), Coates (US Pat. 4,695,578) and Tyers (US Pat. 4,835,173), each taken alone or in combination with each other when similar utilities are asserted.

MPEP § 2144.04 VII provides:

“Pure materials are novel vis-à-vis less pure or impure materials because there is a difference between pure and impure materials. Therefore, the issue is whether claims to a pure compound are unobvious over the prior art. *In re Bergstrom*, 427 F.2d 1394, 166 USPQ 256 (CCPA) 1970). Purer forms of known products may be patentable, but the mere purity of a product, by itself, does not render the product unobvious. *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989).

Factors to be considered in determining whether a purified form of an old product is obvious over the prior art include whether the claimed chemical compound or composition has the same utility as closely related materials in the prior art, and whether the prior art suggests the particular form or structure of the claimed material or suitable methods of obtaining that form or structure. *In re Cofer*, 354 F.2d 664, 148 USPQ 268 (CCPA 1966).”

The CCPA in *In re Cofer* addresses the issue whether a claim to free flowing crystals of 2,2-bis(2,3-epoxypropoxyphenyl) propane is deemed obvious as merely directed

to an old compound with a more pure form. The prior art was alleged by the examiner (and agreed by the board) to have disclosed the claimed product. The board reasoned that "that merely changing the form, purity or another characteristic of an old product, the utility remaining the same as that for the old product, does not render the claimed product patentable." *Id.* at 271.

The CCPA reversed the board's ruling and expressly stated that:

"Merely stating that a compound or composition is obvious, without adequate factual support, is not sufficient." *Id.* at 271.

The CCPA further set forth the controlling rule in determining obviousness under 35 U.S.C. § 103:

"To be sure, whether a given chemical compound or composition has the same usefulness as closely related materials may be an important consideration in determining obviousness under 35 USC 103. But it is not the only consideration. We think the board failed to address itself to other factors which must be given weight in determining whether the subject matter as a whole would have been obvious, namely whether the prior art suggests the particular structure or form of the compound or composition as well as suitable methods of obtaining that structure or form. The new form of the compound set forth in the claims is as much a part of the "subject matter as a whole" to be compared with the prior art as are other properties of the material which make it useful." *Id.* at 271.

Furthermore, the *In re Cofer* factors have also been adopted by The Board of Patent Appeals and Interferences. In *Ex parte Stern* 13 USPQ2d 1379 (Bd. Pat. App. & Inter. 1987), the Board held the claims directed to interleukin 2 purified to homogeneity unpatentable. The 35 U.S.C. § 103 rejection was based on references which recognized the desirability of purifying interleukin 2 to homogeneity and a reference (Pestka reference) taught a method of purifying proteins having molecular weights in excess of 12,000 to homogeneity, wherein the Pestka method was similar to the method disclosed by appellant for purifying interleukin 2.

Here, neither the Chen article nor the '115 patent, '578 patent and '173 patent, each taken alone or in combination with each other, disclose exo-methylene by-products in relation to ondansetron, let alone their identities (i.e., 1,2,3,9-tetrahydro-9-methyl-3-methylene-4H-carbazol-4-one and the dimeric exo-methylene by-product). None of the cited art suggests or teaches a method of removing the exo-methylene by products. In fact, there is no suggestion or teaching regarding any methods of obtaining ondansetron that is substantially free of these exo-methylene by-products.

A compound in purer or modified form may, if unobvious in that form, be patentable over the same compound as it existed in the prior art but the claims thereto must be limited so as to exclude from the scope thereof the compound as it existed in the prior art. *Ex parte Hillyer et al.* 102 USPQ 126 (POBA 1953); *In re Kebrich* 96 USPQ 411 (CCPA 1953); and *Ex parte Frohardt et al.* 139 (USPQ 377 (POBA 1962). Here, claims 1-3 and 42-47 are limited to ondansetron with a purity of at least about 99.0%. These claims exclude from the scope thereof ondansetron as it existed in the prior art.

For at least these reasons, it is respectfully submitted that claims 1-3 and 42-47 are not obvious over Chen, '115 patent, '578 patent and '173 patent. Accordingly, withdrawal of the rejection of claims 1-3 and 42-47 under 35 U.S.C. § 103(a) is respectfully requested.

### **Conclusion**

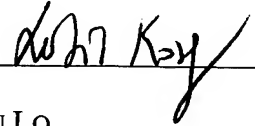
Applicants respectfully that a timely Notice of Allowance be issued in this case. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is urged to telephone the undersigned at (212) 908-6018.

Appl. No. 10/045,970  
Amdt. Dated October 8, 2003  
Reply to Office Action of April 8, 2003

RESPECTFULLY SUBMITTED  
KENYON & KENYON

DATED: OCTOBER 8, 2003

BY:

A handwritten signature in black ink, appearing to read 'Siu Lo', is written over a horizontal line.

SIU LO  
REG. NO. 46,877